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**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Application Number: 10/731,868
Filing Date: December 09, 2003
Appellant(s): SINGHAL ET AL.

Daniel T. Lund
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed September 3, 2009 appealing from the Office action mailed March 31, 2009.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

No amendment after final has been filed.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

6,648,914	BERRANG ET AL	11-2003
6,427,086	FISCHELL ET AL.	7-2002
2003/0109903	BERRANG ET AL	6-2003

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 12 and 27 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claims 12 and 27 each recite creating a recess and placing the device in the recess **in combination** with placing the device in a pocket (see claims 1 and 26). Paragraph 51 only describe an alternative placement method for the device and fails to suggest or explain how a recess could be used in conjunction with the pocket.

Claims 12 and 27 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the

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invention. The combination of placing the device in a pocket **and** placing the device in a recess is not explained in the specification. Furthermore it would not have been readily apparent how a recess could be formed in the pocket (as defined in the specification) such that the device is implanted in both the pocket and recess.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-7,9-12,15-17,24-32 rejected under 35 U.S.C. 103(a) as being unpatentable over Fischell et al. USPN 6427086 in view of Berrang et al. USPN 6648914 ("Berrang '914") and Berrang US PUB 2003/0109903 (Berrang '903").

Fischell et al. disclose implanting a low profile medical device between a scalp and cranium at the top of the head (see Figure 23). The device may comprise a neurostimulator with brain leads, may be secured via bone screws, and may be implanted in a recess (see abstract and column 31 lines 60- column 32 line 52). Fischell et al. lacks the express disclosure of the implantation steps (claims 1,11,25-29,31), or the specific dimensions of the device recited in claims 2-6.

Berrang '914 teach implantable devices for placement between the scalp and cranium wherein the device includes a control module divided into two modules covered by a flexible overmold (claim 2), thickness of about 4-8mm (claim 3), and a peripheral

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edge angle of about 135 degrees (claims 5-6) in order to provide the device with cranium conformable features. The implantation steps include administering local anesthetic (claim 17), making a C-shape incision (claim 31), and creating a pocket behind the incision (figure 3) to place the device in the pocket.

Berrang '903 teach implantable devices for placement between the scalp and cranium wherein the device includes a periphery angle of about 135 degrees and wherein the thickness is about 6 mm, and where a flap/pocket method is used (see figure 1-3 and paragraph 46).

Regarding claim 11, the step of suturing a flap would have been readily apparent to close to the flap incisions taught by each of Berrang '814 and Berrang '903.

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the device and method of implantation disclosed in Fischell et al. to include the features and steps of Berrang '914 and Berrang '913 in order to provide a low profile, conformable implantation procedure. Furthermore it is well within the level of one of ordinary skill in the art to apply surgical steps known in the art.

(10) Response to Argument

Appellant's arguments with respect to claims 1-7,9-12,15-17,24-32 have been considered but are not persuasive. Appellant divides Grounds of Rejection (1) - (3) into further groups labeled 1 through 11, each separately addressed below.

Lack of Written Description, Claims 12 and 27 (First Ground and Group 1)

Appellant argues at page 11, first paragraph, that the claims do not require a recess beneath the pocket (i.e. at the same location on the scalp), and that a portion of

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the device could be in a pocket and another portion in a recess. Examiner respectfully disagrees.

The independent claims require at least a portion of the device in the pocket and dependent claims 12 and 27 require placing the device in the recess. During prosecution, Appellant argued that the specification disclosure of "placing the device or a portion thereof in the pocket" supported placing the "entire device" or "a portion of the device" in a pocket, and Examiner agreed. Similarly, the scope of "placing the device in the recess" should be interpreted to include, or encompass, placing the whole device in the recess and a portion in the pocket (i.e. both the recess and pocket are claimed to be at same location).

The specification is silent as to creating a pocket and recess at the same location, and how such a method would be performed. The specification merely describe a detailed method of pocket formation to receive an IMD (implantable medical device), an optional step of inserting a "dummy IMD" prior to placement of the actual IMD (paragraph 0046), and later at paragraph 0051 it is disclosed that an optional recess in the skull could be formed to accommodate an IMD. The recess is described, for example, in situations where the IMD profile is not thin enough to lie over the skull. The recess is not described in connection with the pocket, and it is unclear how the two steps would be combined in a single procedure. Examiner maintains that paragraph 0051 describes an alternative method because there is no logical reason to create a pocket (by sliding a spatula under an intact scalp), and then creating a recess under said pocket. Typically, if a recess in the skull is desired then the scalp is exposed to

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allow removal of the skull bone. The specification as a whole describe a method for placing low-profile IMDs in a pocket between the scalp and skull, or placing a larger profile IMD in a recess in the skull. The two methods appear separate and distinct, and the specification fails to provide clear written support of a method including placing an entire device in a recess while at least a portion of the device is within a pocket as defined in the specification.

Lacking Enablement, Claims 12 and 27 (Second Ground and Group 2)

Appellant argues again at page 12, second paragraph, that the claims do not require a recess beneath the pocket (i.e. same location), but attempts to explain how it would be readily apparent to one of ordinary skill to create a recess under a pocket with a bone chisel or rotary bit. However, the prior art known to the Examiner exposes the skull before carving out a recess therein. Appellant improperly suggests the step of making a recess underneath an intact existing scalp (and under the pocket), sufficient in size to accommodate the entire IMD device, is readily apparent and does not require any explanation. Examiner disagrees. Appellant describes a spatula is used to create the pocket, thus it is unclear how a tool would be utilized to form a recess therein. To receive such a tool it would seem the pocket must be separated from the scalp to provide space (such as shown in Berrang '914 figure 3) to provide room for a recess forming tool, but Appellant has argued throughout prosecution history that Berrang doesn't teach a pocket, but rather a large flap. Therefore, either the pocket would be eliminated to create the recess or the skull is somehow removed under an intact scalp. Appellant suggests a "bone chisel or rotary bit" could be used to create a recess under

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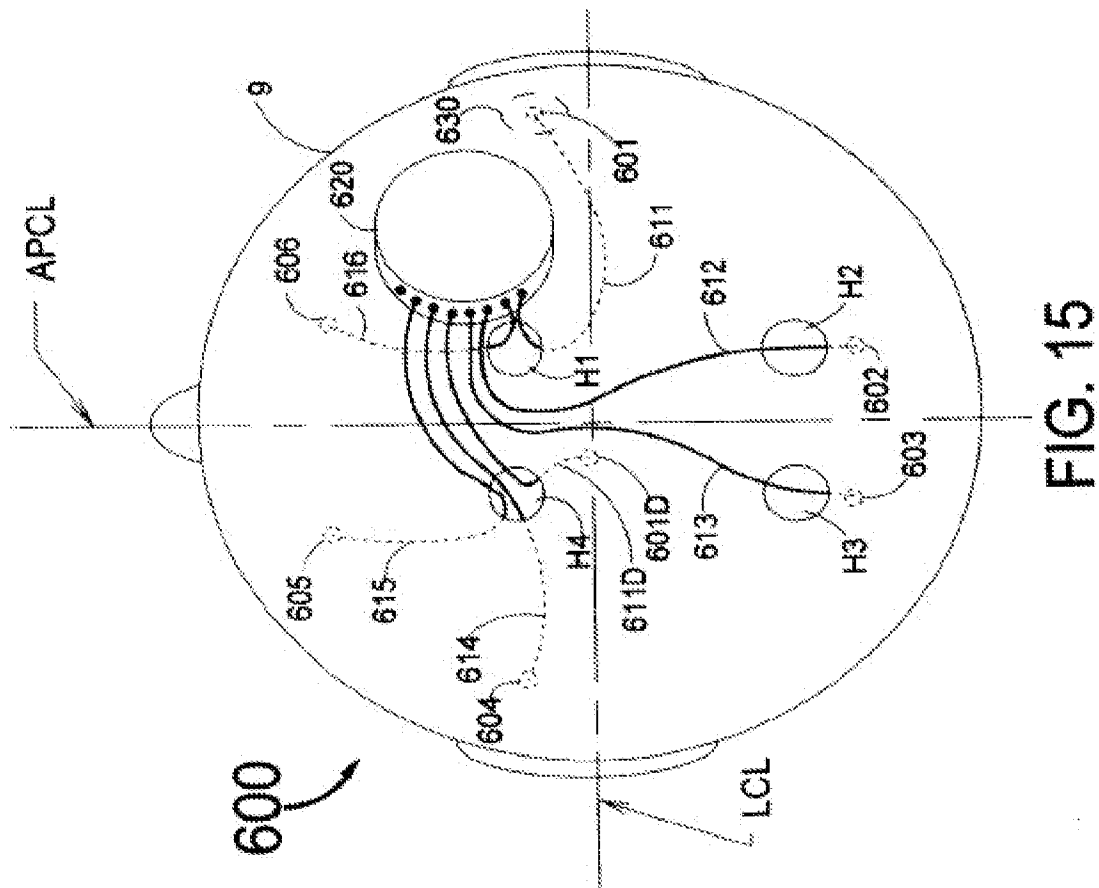
the pocket (brief page 13, first paragraph). However it is unclear if such chiseling or drilling would damage the scalp as the bone adjacent the scalp is removed, or eliminate the pocket as described in the specification.

Appellant further argues that "placing the device in a recess" doesn't include "the entire device". See Brief, paragraph spanning pages 12-13 and the next paragraph. As noted above with Group 1, Examiner maintains that placing "the device" encompasses the entire device or a portion thereof. Thus the claims encompass placing at least a portion of the device at a single location have both a pocket and a recess, and Appellant has not sufficiently enabled one of ordinary skill in the art to create both at the same location on a skull.

Claims 1-7,9-11,15,17,24, and 30 (Third Ground, Group 3)

A. Drilling Burr holes under the flap (Brief page 15, first paragraph)

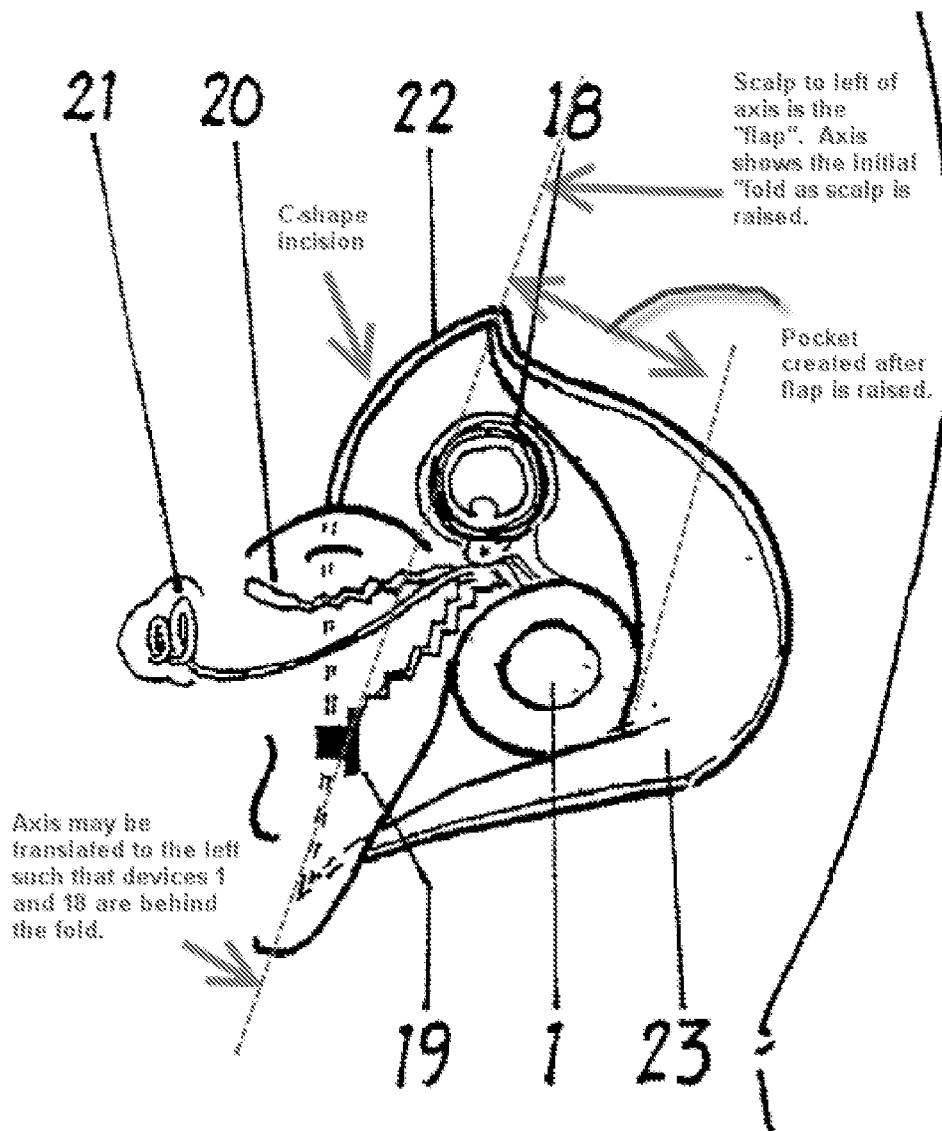
Appellant argues the specification of Fischell teach tunneling the wires under the scalp before reaching a hole. Examiner pointed to hole H1 in figure 15 (see below), but Appellant argues the figure contradicts the specification teachings and can't be relied upon. Examiner disagrees because the figures clearly show the holes may be close to the device (H1) or further away (H2-H3), and column 29 lines 21-48 clearly describe the distinctions between placement of wires 612/613 versus wire 616. Thus tunneling is not required before passing through hole H1.



B. Pocket adjacent the fold and between the scalp and skull (Brief, pages 15-16)

Appellant argues Berrang fails to teach a pocket adjacent the fold and between the scalp and skull. Thus the combination of Fischell and Berrang PUB '903 and Berrang PAT '914 fails to teach all steps of the method. Examiner disagrees. Each of the Berrang Applications show:

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As shown above, Berrang PUB and PAT each teach the following steps expressly or inherently:

1. C-shaped incision 22 is formed.
2. The flap to the left of the dashed line is raised and a fold would be inherently present essentially along the dashed line where the scalp is still intact with the skull.
3. Further raising of the scalp creates a pocket behind, or to the right of the initial fold.

4. The device is placed in this pocket.

Appellant argues the claims require forming the pocket after the step of raising the flap which is not performed in the Berrang methods. Examiner disagrees because a single motion of the surgeon's hand performs steps 2 and 3 above, and in the order as claimed.

Claim 12 (Third Ground, Group 4) Brief, page 17

Appellant argues Fischell teaches removing all of the skull bone to create a hole, and therefore it's not a recess. Examiner disagrees because the claims do not require the recess to be only partially through the skull.

Claim 16 (Third Ground, Group 5) Brief, pages 17-18

Appellant argues the references fail to teach "adjusting the device to more closely match the contour of the skull". Appellant further argue Examiner failed to explain how the references suggest such a step. Examiner disagrees because Fischell discloses the device to match a contour of the skull throughout the disclosure (abstract, or the technique of placing the device in a recess), so the mere placement of the device would encompass adjusting the device to match the contour of the skull.

Claim 25 (Third Ground, Group 6) Brief, pages 18-19

Appellant argues the references do not teach placement of the entire device in the pocket. Initially, Examiner notes the specification is not clear with respect to what structures are considered to be the "device". Appellant's figures and claims require wire leads to extend out of the pocket, thus Examiner believes the limitation of "placing the entire device in the pocket" is equivalent to placing a portion of the entire apparatus within the pocket. Appellant's Figure 4 is closest to showing an entire device in a pocket but there are several wires/sensors outside of the pocket. Therefore it would be proper to consider the entire device of Berrang being placed in the pocket because either a) at least one of the major portions is completely in the pocket or b) the axis defining the fold and pocket shown above may be translated to the left because during the step of raising the flap, the fold line would shift to the right.

Claim 31 (Third Ground, Group 7) Brief, pages 19-20

Appellant argues Berrang teaches an "S-shaped" incision rather than C-shaped as claimed, and that a C-shaped incision would provide a clearly defined fold. Examiner disagrees because Berrang's figures clearly show an S-incision which includes a C-incision. The claims use the transitional phrase "comprising" and are thus not limited to only a C-shaped incision.

Claim 26 (Third Ground, Group 8) Brief, pages 20-21

The arguments are the same as for claim 25 (Group 6) above, and Examiner maintains the response above under Group 6.

Claim 27 (Third Ground, Group 9) p21-22

The arguments are the same as for claim 12 (Group 4) above, and Examiner maintains the response above under Group 4.

Claims 28 and 32 (Third Ground, Group 10) Brief, pages 22-23

Initially, it is noted that claim 28 is the broadest independent claim.

The arguments are the same as for Group 3 part B above, but Appellant adds further reasoning. Appellant argues the Berrang device is not placed in a pocket behind a fold. Appellant argues that Berrang Figure 3 (shown above) has a fold on the rightmost side of the figure and the device is not in a pocket behind the incision, but rather in front of it. Appellant points to the Berrang disclosure that describes a) making incision, b) raising a flap, and c) inserting the device under the flap. In response, Examiner maintains that a single step of raising the scalp flap inherently creates a fold before the pocket is created, and the end result is a pocket to the right of a fold.

Claim 29 (Third Ground, Group 11) pages 23-24

The arguments are the same as for Groups 6 and 8 above ("placing entire device in the pocket") and Appellant repeats the arguments of Group 3, part B as they relate to independent claim 28 in Group 10 above. Examiner maintains the response detailed above because the Berrang method performs steps 1-4 outlined above under Group 3, part B.

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(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

/William H. Matthews/

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